COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF ENVIRONMENTAL AFFAIRS
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ONE WINTER STREET, BOSTON, MA 02108 617-292-5500

MITT ROMNEY
Governor

KERRY HEALEY
Lieutenant Governor

ELLEN ROY HERZFELDER
Secretary

ROBERT W. GOLLEDGE, Jr.
Commissioner

MASSACHUSETTS

WATER POLLUTION CONTROL
314 CMR 17.00

and

CERTIFICATION OF OPERATORS OF WASTEWATER TREATMENT FACILITIES
257 CMR 2.00

PUBLIC HEARING DRAFT

Industrial Wastewater Management
for Biotechnology Operations

May 2005

Prepared by: ***The Commonwealth of Massachusetts***
Executive Office of Environmental Affairs
Department of Environmental Protection
Bureau of Waste Prevention

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Dear Citizen:

I am pleased to send you this copy of the public hearing draft of 314 CMR 17.00, the proposed new Industrial Wastewater Management for Biotechnology Operations Regulations of the Department of Environmental Protection (the "Department"). Also included is a copy of the public hearing draft of a proposed related amendment to 257 CMR 2.00, the Certification of Operators of Wastewater Treatment Facilities Regulations. These latter regulations are administered by the Board of Registration of Operators of Wastewater Treatment Facilities (the "Board"), and are being amended concurrently by the Board.

After reviewing these public hearing drafts, I hope that you will comment and attend one of the six public hearings to be held by the Department and the Board June 23 through 30, 2005; the public comment period will end on July 11, 2005. The Department and the Board would like to receive your comments and suggestions on how we can most effectively implement this new, more streamlined, approach to regulating industrial wastewater discharges from biotechnology operations.

Please contact John Reinhardt at (617) 292-5667 or Lee Dillard Adams (508) 767-2775 if you have questions you would like to ask prior to the hearings. We hope you can attend and look forward to receiving your input.

Very truly yours,

James C. Colman
Assistant Commissioner
Bureau of Waste Prevention

The Commonwealth of Massachusetts
Executive Office of Environmental Affairs
Department of Environmental Protection
and the Board of Certification of Operators of Wastewater Treatment Facilities

PUBLIC HEARINGS NOTICE

The Department of Environmental Protection is holding public hearings on proposed amendments to: 310 CMR 30.0000, (the Hazardous Waste regulations, adopted pursuant to M.G.L. Chapter 21C); and 310 CMR 7.00 (the Air Quality regulations, adopted pursuant to M.G.L. Chapter 111, §§142 A-N), as well as proposed new regulations at 314 CMR 17.000 (Industrial Wastewater Management for Biotechnology Operations, adopted pursuant to M.G.L. c. 21, §§26 through 53). In addition, the Board of Certification of Operators of Wastewater Treatment Facilities is holding simultaneous public hearings on proposed amendments to 257 CMR 2.00 (the Certification of Operators of Wastewater Treatment Facilities regulations, adopted pursuant to M.G.L. c. 21, §34A and §34B).

The proposed or amended DEP regulations are organized into three regulatory packages.
Amendments to the Hazardous Waste Regulations consisting of:

- Provision for conditional waiver of requirements for elementary neutralization of hazardous waste by Generators in tanks and containers, and
- Provision for a case-by-case waiver determination process that would allow the Department to grant waivers for specific wastes and activities that are either adequately regulated or insignificant as a potential hazard (for wastes and activities not regulated by U.S. EPA under the federal Resource Conservation and Recovery Act);

Amendments to the Air Pollution Control regulations, consisting of:

- Plan Approval exemption for Biotechnology Surface Disinfection Processes, that is intended to provide a permit-by-rule for emission of volatile organic compounds from biotechnology operations' surface disinfection processes; and
- Plan Approval exemption for Biotechnology Laboratories; and

New Industrial Wastewater Management for Biotechnology Operations regulations and an amendment to the Certification of Operators of Wastewater Treatment Facilities regulations:

- These regulatory changes are intended to provide a permit-by-rule for discharge of industrial wastewater to the sewer and for pretreatment of industrial wastewater as well as exempt persons who manage, operate and maintain wastewater treatment facilities in compliance with 314 CMR 17.00 from obtaining a separate approval from the Board of Certification under 257 CMR 2.00.

Public hearings on the proposed amendments will be conducted under the provisions of Chapter 30A of the Massachusetts General Laws on:

Thursday, June 23, 2005 - Springfield - 1:00 p.m. - Department of Environmental Protection, Western Regional Office, 436 Dwight St., Room 305, 3rd Floor Courtroom, Springfield, MA

Friday, June 24, 2005 - Boston - 10:00 a.m. - Department of Environmental Protection, One Winter Street, 2nd Floor, Atlantic Room, Boston, MA

Monday, June 27, 2005 - Worcester - 3:00 p.m. - Department of Environmental Protection, Central Regional Office, 627 Main St., Commissioner's Conference Room, Worcester, MA

Tuesday, June 28, 2005 - Boston – 1:30 p.m. - Department of Environmental Protection, One Winter Street, 2nd Floor, Atlantic Room, Boston, MA

Wednesday, June 29, 2005 - Lakeville - 1:00 p.m. - Department of Environmental Protection, Southeast Regional Office, 20 Riverside Dr., 1st Floor Conference Room, Lakeville, MA

Thursday, June 30, 2005 - Boston - 10:00 a.m. - Department of Environmental Protection, One Winter Street, 2nd Floor, Atlantic Room, Boston, MA

Testimony may be presented orally or in writing at the public hearings. In addition, written comments will be accepted **until 5:00 p.m. on July 11, 2005** at the Department of Environmental Protection, 627 Main Street, Worcester, MA 01608, attention: Lee Dillard Adams.

Copies of the regulation amendments and background documents are available on the DEP website at http://www.mass.gov/dep/bwp/biotech.htm and during normal business hours at the DEP Boston Info Center or DEP's Regional Service Centers:

DEP Boston Info Center, One Winter Street, Boston (800) 462-0444
DEP Southeast Region, 20 Riverside Drive, Lakeville (508) 946-2714
DEP Western Region, 436 Dwight Street, Suite 402, Springfield (413) 784-1100 x 2214
DEP Central Region, 627 Main Street, Worcester (508) 792-7683

This information is available in alternate format upon request to: ADA Coordinator, 4th floor, One Winter Street, Boston, 02108 at (617) 556-1057. For special accommodations for this event, call (617) 348-4056.

By order of the Department

Robert W. Golledge, Jr., Commissioner

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I. Introduction

The Department of Environmental Protection (DEP) is proposing regulations at 314 CMR 17.00 that set discharge standards and management requirements for certain biotechnology operations that discharge industrial wastewater to the sewer system of a Publicly Owned Treatment Works (POTWs) with a U.S. EPA approved Industrial Pretreatment Program (IPP), other than the Massachusetts Water Resources Authority (MWRA) system.[1] 314 CMR 17.00 would set minimum state numerical effluent limits and management standards for industrial wastewater discharges as well as grading and staffing requirements for seven industrial wastewater treatment systems commonly used in the biotech industry. The proposal also includes a registration and one-time compliance certification. The performance standards and other requirements in 314 CMR 17.00 would serve as a permit-by-rule, and biotechnology operations that meet the criteria for regulation under 314 CMR 17.00 and maintain compliance with the regulation would be exempt from obtaining the otherwise required state sewer discharge permits, industrial wastewater treatment facility plan approvals and grading, and certified operator staffing plan approvals.

II. To What Biotech Operations do the Regulations Apply?

314 CMR 17.00 would apply to biotechnology operations that meet all of the following criteria:

(a) the biotechnology operation makes a medical device, drug, or biologic product derived in whole or in part from biotechnology, and one of the following applications or notices has been filed with FDA for such product: an Investigational New Drug Application, an Investigational Device Exemption Notice, a New Drug Application, premarket approval application, or premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) (including an FDA-approved exemption from the 510(k) premarket notification requirement);

(b) the biotechnology operation discharges industrial wastewater into a POTW with an Industrial Pretreatment Program, as defined in 40 C.F.R. 403, that has been approved by EPA;

(c) the biotechnology operation has submitted a complete and timely *Registration and One-time Compliance Certification Statement* to the Department, the local sewer authority, and the Board.

314 CMR 17.00 would not apply to biotechnology operations that discharge industrial wastewater into the sewer system of a local or regional sewer authority that has received the Department's approval to administer state sewer discharge permits. At present, the MWRA is the only sewer authority that has been delegated authority by the Department to administer state sewer discharge permits. Biotechnology operations that discharge industrial wastewater into the MWRA system are not subject to 314 CMR 17.00 and

[1] DEP has delegated authority for administering the state sewer discharge permit program to the MWRA pursuant to 314 CMR 7.16. Consequently, biotech companies that discharge to the MWRA system are not subject to DEP issued sewer discharge permits and therefore, are not subject to this permit by rule.

would continue to be regulated by the MWRA. Lastly, biotechnology operations that discharge to a POTW without an EPA-approved Industrial Pretreatment Program are also not subject to 314 CMR 17.00, and would continue to be subject to state industrial wastewater sewer discharge permit program.

III. What are the Key Provisions of the Regulation?

Minimum statewide numerical effluent limitations and monitoring requirements

All industrial wastewater discharges to POTWs from biotechnology operations subject to 314 CMR 17.00 would need to comply with the discharge limits and other requirements of the sewer use regulations of the local sewer authority and the applicable provisions of EPA's regulations at 40 C.F.R. Part 403. More specifically, 314 CMR 17.06 would provide that such discharges must comply with the more stringent of the local effluent limit or the minimum state effluent limits listed in 17.06(2)(b). The statewide limits in the regulation are intended to complement POTW Industrial Pretreatment Program efforts to prevent pass-through, interference or operational problems.[2] Local sewer authorities sometimes set stricter limits that reflect local conditions. In addition to effluent limitations, the regulation would set monitoring requirements and specify the sampling frequency and analytical methods to be used.

Industrial wastewater treatment system: grading, staffing plans, operation and maintenance, and recordkeeping requirements

314 CMR 17.08 would assign grades and exempt from plan approval requirements seven types of industrial wastewater treatment systems in several configurations. 314 CMR 17.09 would establish staffing requirements for certified operators for these systems, and special consideration is given both to systems that are alarmed and to those that are fully automated. In addition, the regulation allows a biotechnology operation to propose an alternative-staffing plan for the Department's approval. Finally, 314 CMR 17.10 would set requirements for the operation and maintenance manual and 314 CMR 17.11 would establish recordkeeping requirements for the management, operation and maintenance of the industrial wastewater treatment system, effluent monitoring, and staff training.

[2] DEP reviewed the local industrial sewer user discharge limits established by each of the 47 POTWs in Massachusetts with a US EPA approved Industrial Pretreatment Program. These local limits address a wide range of environmental and operational considerations and therefore have great variability. In establishing the proposed state-wide numeric standards, DEP analyzed the local limit data using four different criteria with the goal of establishing appropriate standards that complement POTW efforts to protect against treatment plant pass through, interference, or operational problems. For each parameter, the proposed state-wide numeric limit is based on the most stringent of the following: (1) a limit below the threshold that defines a hazardous waste; (2) 200% of the average of the limits set by the POTWs; (3) 10% of the least stringent local limit; and (4) for parameters for which fewer than 10 POTWs have established limits, the second least stringent limit. Appendix A provides a summary of this data.

Reporting requirements

The reporting section at 314 CMR 17.12 specifies how frequently reports of effluent monitoring and exceedances would need to be provided to the local sewer authority (and to DEP upon request). As a precondition to being regulated under 314 CMR 17.00, a biotechnology operation would have to file a *Registration and One-time Compliance Certification Statement* (collectively, the "Registration") with the Department, the local sewer authority, and the Board of Registration of Operators of Wastewater Treatment Facilities.

IV. Will this State Regulation Affect Permits and Other Limits Issued by Local Sewer Authorities?

314 CMR 17.00 would not affect the independent authority of local sewer authorities to issue permits or set local discharge limits. The regulations would make clear that biotechnology operations must comply with any permit, discharge limits, and other requirements of local sewer use regulations. In any case where a the local authority sets a discharge limit for a parameter which is also limited in 314 CMR 17.06(2)(b), the regulation would require compliance with the more stringent of the two.

V. Why Is The Department Adopting These Regulations?

Biotechnology is a growing industry in Massachusetts and one that is being looked to for further economic growth. 314 CMR 17.00 is intended to protect public health, safety, and the environment by providing clear, measurable, and consistent standards by which biotech operations will be regulated. The regulation would establish minimum effluent limits to complement limits set by local sewer authorities.

VI. Under What Authority Will These Regulations Be Adopted?

314 CMR 17.00 would be promulgated by the Department pursuant to its authority under the Massachusetts Clean Waters Act, M.G.L. c. 21, §§ 26 through 53. These regulations are being adopted in accordance with M.G.L. c. 30A.

VII. What is the Purpose and Effect of the Related Amendment to 257 CMR 2.00 Certification of Operators of Wastewater Treatment Facilities?

The proposed concurrent amendment to the Board of Registration of Operators of Wastewater Treatment Facilities (the "Board") Regulation at 257 CMR 2.04(2) would provide that persons who manage, operate and maintain a wastewater treatment facility in compliance with the certified operator and classification of wastewater treatment facilities provisions in 314 CMR 17.00 are exempt from obtaining approval from the Board for such certified operator and facility classification requirements as specified in 314 CMR 17.00. This amendment is necessary to ensure that 314 CMR 17.00 and 257 CMR 2.00 do not conflict with each other.

VIII. Proposed Regulation: 314 CMR 17.00 Industrial Wastewater Management for Biotechnology Operations

17.01 Purpose

The purpose of 314 CMR 17.00 (Industrial Wastewater Management for Biotechnology Operations) is to provide uniform, minimum state regulatory standards applicable to certain biotechnology operations in Massachusetts that discharge industrial wastewater into a Publicly Owned Treatment Works with an EPA-approved Industrial Pretreatment Program. Biotechnology operations that meet the criteria for regulation under 314 CMR 17.00 and maintain compliance with this regulation are exempt from obtaining the Department permits and approvals specified in 314 CMR 17.04.

17.02 Definitions

For the purposes of 314 CMR 17.00, the following terms shall have the following meanings, unless the context clearly requires otherwise:

Alarmed Industrial Wastewater Treatment System (AIWTS) means a treatment system that is equipped with alarms to indicate potential malfunctions that could impact effluent limitation compliance, that annunciate at a location staffed during operating hours of the system, resulting in execution of an on-call system that causes an on-site response by an appropriately licensed operator of the subject industrial wastewater treatment system in a timely manner.

Biotechnology means the use of cellular and molecular processes from living systems to make or assist in making products.

Biotechnology Operation means any site or works, or portion of a larger site or works, where biotechnology processes are located and conducted, and from which industrial

wastewater is or will be generated, stored, treated, dewatered, refined, incinerated, reclaimed, stabilized, solidified, disposed, or otherwise processed.

Board means the Board of Registration of Operators of Wastewater Treatment Facilities established in M.G.L. c. 21, § 34A. The Board evaluates and certifies operators of wastewater treatment facilities pursuant to 257 CMR 2.00.

Clean untreated non-contact cooling water means water used to reduce temperature that does not come into direct contact with any biocide, raw material, intermediate product, waste product (other than heat), or finished product.

DEP or Department means the Massachusetts Department of Environmental Protection.

EPA means the United States Environmental Protection Agency

Existing Biotechnology Operation means an ongoing biotechnology operation that was operational prior to the promulgation date of 314 CMR 17.00.

Fully Automated Industrial Wastewater Treatment System (FAIWTS) means a treatment system that is equipped with treatment process controller(s), which are capable of initiating, conducting and completing wastewater treatment process automatically according to preset control parameters and treatment processes. In addition, an FAIWTS must be also capable of responding to any potential system malfunctions that could impact effluent compliance, including, but not limited to automatic system shutdown, switch the incoming flow to a temporary holding device or recirculating when necessary, sending appropriate alarm signals to a staffed location during the operating hours, or resulting in execution of an on-call system that notify a responsible operator in a timely manner.

Industrial Wastewater means any waste in liquid form resulting from any process of industry, trade or business, regardless of volume or pollutant content. Waste in liquid form consisting of only sewage is not industrial wastewater.

Industrial Wastewater Pretreatment means the reduction of the amount of pollutants, the elimination of pollutants, or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing such pollutants into a POTW.

Industrial Wastewater Treatment System or IWTS means any and all devices, processes and properties, real or personal, used in the collection, pumping, transmission, storage, treatment, disposal, recycling, reclamation or reuse of waterborne pollutants, but not including any works receiving a hazardous waste from off the site of the works for the purpose of treatment, storage or disposal, or holding tanks regulated under 314 CMR 17.00.

New Biotechnology Operation means a biotechnology operation that commences operation on or after the promulgation date of 314 CMR 17.00.

Pretreatment Facility means any site or works where the reduction of the amount of pollutants, the elimination of pollutants, or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing such pollutants into a POTW.

Publicly Owned Treatment Works or POTW means any device or system used in the treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature that is owned by a public entity. A POTW includes any sewers, pipes, or other conveyances only if they convey wastewater to a POTW providing treatment.

Standard Methods for the Examination of Water and Wastewater means methods referenced and described in the latest edition of the technical reference book entitled *Standard Methods for the Examination of Water and Wastewater*. The Standard Methods for the Examination of Water and Wastewater sets forth approved methods for the examination of water and wastewater, the proper collection, preservation, laboratory procedures, and other conditions to help establish credible results from testing. It is published and updated periodically by the American Public Health Association (APHA), the American Water Works Association (AWWA), and the Water Pollution Control Federation (WPCF).

State Act means the Massachusetts Clean Waters Act, as amended, M.G.L. c. 21, §§ 26 through 53.

17.03 Applicability

(1) 314 CMR 17.00 shall apply to biotechnology operations that meet all of the following criteria:

(a) the biotechnology operation is used in making a medical device, drug, or biologic product derived in whole or in part from biotechnology, and one of the following applications or notices has been filed with FDA for such product: an Investigational New Drug Application, an Investigational Device Exemption Notice, a New Drug Application, premarket approval application, or premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) (including an FDA-approved exemption from the 510(k) premarket notification requirement);

(b) the biotechnology operation discharges industrial wastewater from such operations into a POTW with an Industrial Pretreatment Program, as defined in 40 C.F.R. 403, that has been approved by EPA; and

(c) the biotechnology operation has submitted a complete and timely *Registration and One-time Compliance Certification Statement* pursuant to 314 CMR 17.12(3) to the Department, the local sewer authority, and the Board.

(2) 314 CMR 17.00 shall not apply to biotechnology operations that discharge industrial wastewater into a POTW of a local or regional sewer authority that has received the Department's approval under 314 CMR 7.16 to administer sewer connection permits pursuant to the State Act.

(3) 314 CMR 17.00 should be read together with 105 CMR 480 (Department of Public Health regulations on the Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste) and 248 CMR 2.13 (the Piping and Treatment of Special Waste section of the Uniform State Plumbing Code) that contain other requirements applicable to industrial wastewater discharges from biotechnology operations. No provision in 314 CMR 17.00 is intended to modify or affect the regulation of applicable wastes under 105 CMR 480 and 248 CMR 2.13.

17.04 Exemptions

(1) A biotechnology operation that meets the applicability criteria in 314 CMR 17.03(1) and is in compliance with 314 CMR 17.00 is exempt from the following Department permits and approvals:

(a) A sewer connection permit under 314 CMR 7.00;

(b) Department approval of the treatment works under M.G.L. c. 111, §17;

(c) Department approval of major physical modifications of treatment works under 314 CMR 12.03(1);

(d) Department approval of an increase in volume of discharge to a treatment works under 314 CMR 12.03(2);

(e) Department approval of treatment plans under 314 CMR 12.03(4); and

(f) Department approval of a staffing plan for the treatment works under 314 CMR 12.04(3).

(2) The Board's regulations at 257 CMR 2.04(2) provides that persons who manage, operate and maintain a wastewater treatment facility in compliance with the certified operator and classification of wastewater treatment facilities provisions in 314 CMR 17.00 are exempt from obtaining approval from the Board of Registration of Operators of Wastewater Treatment Facilities for such certified operator and facility classification requirements as specified in 314 CMR 17.00. **[Note: inclusion of this informational provision is predicated on the Board amending its regulations on or before the date that 314 CMR 17.00 is promulgated.]**

17.05 General Requirements

The following general requirements apply to a biotechnology operation regulated under 314 CMR 17.00:

(1) All discharges to a POTW shall, at a minimum, comply with the discharge limits and other requirements of the sewer use regulations of the local sewer authority and the applicable provisions of 40 C.F.R. Part 403.

(2) The discharge of water-borne animal bedding from cage washing operations to a POTW is prohibited.

(3) A biotechnology operation shall not discharge clean untreated non-contact cooling water to a POTW, unless the local sewer authority expressly authorizes such discharge.

(4) A new biotechnology operation shall have an industrial wastewater treatment system or a major system upgrade in place that has been constructed in accordance with engineering plans stamped and signed by a Massachusetts Registered Professional Engineer.

(5) An existing biotechnology operation shall have an industrial wastewater treatment system or a major system upgrade in place that has been constructed in accordance with engineering plans stamped and signed by a Massachusetts Registered Professional Engineer. As an alternative, an existing biotechnology operation may have the existing industrial wastewater treatment system inspected and evaluated by a Massachusetts Registered Professional Engineer, provided that any deficiencies identified during such inspection and evaluation shall be documented in a report to the Department and the local sewer authority and corrected within 30 days of the submittal of the evaluation report.

17.06 Effluent Limits and Requirements

(1) All industrial wastewater discharges from a biotechnology operation shall comply with the more stringent of the effluent limits and requirements in 314 CMR 17.06 (2)(a) and (b).

(2) The more stringent of the following effluent limits and requirements apply to all discharges of industrial wastewater from a biotechnology operation:

(a) all effluent limits and requirements imposed by the local sewer authority and any applicable categorical standards, including but not limited to, the provisions of 40 C.F.R. 405 through 40 C.F.R. 471; and

(b) the minimum state effluent limits for the following pollutants:

1. Ammonia, NH_4	25.0 mg/l
2. Arsenic, As	1.9 mg/l
3. Biological Oxygen Demand, BOD_5	900.0 mg/l
4. Cadmium, Cd	0.9 mg/l
5. Chromium, Cr	4.9 mg/l
6. Copper, Cu	4.4 mg/l
7. Cyanide, CN	1.8 mg/l

8. Lead, Pb	1.8 mg/l
9. Oil and Grease	250.0 mg/l
10. Mercury, Hg	0.08 mg/l
11. Molybdenum, Mo	0.16 mg/l
12. Nickel, Ni	4.0 mg/l
13. Selenium, Se	0.9 mg/l
14. Silver, Ag	1.2 mg/l
15. Total Toxic Organic Chemicals [(3)], TTO	5.0 mg/l
16. Total Suspended Solids, TSS	750.0 mg/l
17. Zinc, Zn	8.3 mg/l
18. pH – Min.	5.5 standard units
19. pH – Max.	11.0 standard units

17.07 Monitoring Requirements

(1) Monitoring Devices

(a) A biotechnology operation shall install suitable control and measuring devices, such as manholes, chambers, meters (e.g., flow, pH), and other appurtenances, necessary for the observation, sampling and measurement of industrial wastewater and pollutant levels.

(b) All control and measuring devices shall be installed at a safe location that is accessible to DEP, EPA, and the local sewer authority personnel and their monitoring equipment.

(c) All control and measuring devices and related appurtenances shall be designed and constructed according to applicable engineering standards and shall be properly maintained and calibrated so as to ensure the accuracy of the measurement.

(2) Monitoring Parameters

(a) A biotechnology operation shall monitor those pollutants and toxic chemicals listed in 314 CMR 17.06(2)(b) in accordance with 314 CMR 17.07(3).

(b) If a biotechnology operation can demonstrate to the Department's satisfaction that certain pollutants or chemicals processed, used, or produced within that operation, including those listed in 314 CMR 17.06(2)(b), have no potential to enter into the industrial wastewater stream, then such pollutants or chemicals shall be exempt from monitoring under 314 CMR 17.07.

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[3] TTO Limit is the sum of the concentration of all Toxic Chemical concentrations that may be in the user's waste stream.

(3) Minimum Monitoring Frequency

(a) At a minimum, the monitoring frequency for all the pollutants and toxic chemicals listed in 314 CMR 17.06(2)(b), except pH, shall be twice per calendar year. The first monitoring event shall occur no later than March 15th. The second monitoring event shall occur no later than September 15th.

(b) The pH shall be continuously monitored during all discharge periods through a pH monitoring and recording system.

(4) Sampling and Analysis Requirements

(a) All measurements, tests, and analyses of the characteristics of industrial wastewater required by 314 CMR 17.00 shall be conducted in accordance with the *Standard Methods for the Examination of Water and Wastewater*, unless otherwise specified by the Department or the local sewer authority.

(b) Any sample analysis required by 314 CMR 17.00 shall be performed by a Department-certified laboratory accredited for the parameters being analyzed.

17.08 Grading of Industrial Wastewater Treatment Systems (IWTS)

(1) Any biotechnology operation that uses an IWTS consisting of a single or dual stage pH adjustment treatment system only shall be exempt from the Department treatment plant plan approval requirements in 314 CMR 12.03(4) and shall be graded as a Grade 1I (one, industrial) system.

(2) Any biotechnology operation that uses an IWTS consisting of only one of the following processes for industrial treatment, with or without a single or dual stage pH adjustment treatment system, shall be exempt from treatment plant plan approval requirements in 314 CMR 12.03(4) and shall be graded as a Grade 2I (two, industrial) system:

(a) cartridge filtration;

(b) cartridge metallic ion replacement;

(c) cartridge single or dual stage ion exchange;

(d) reverse osmosis;

(e) ultra filtration system; or

(f) carbon absorption.

(3) All other IWTS configurations shall be approved and graded in accordance with the provisions of 257 CMR 2.00 and 314 CMR 12.00.

(4) Any sterilization, disinfection, deactivation, or other process or system used by a biotechnology operation solely to render living organisms nonviable prior to discharge to a sewer system shall not be considered a treatment process that is subject to requirements for the grading and operation of industrial wastewater treatment systems under 314 CMR 17.00, 314 CMR 12.00, and 257 CMR 2.00.

17.09 Staffing Requirements for Industrial Wastewater Treatment Systems (IWTS)

(1) A biotechnology operation without an IWTS is not subject to the requirements of 314 CMR 17.09.

(2) A biotechnology operation shall comply with the following staffing requirements:

(a) Operator Grading

i. Each biotechnology operation shall have at least one chief operator and one assistant chief operator. However, the use of additional licensed operators is recommended by the Department to assure adequate staffing in the absence of the chief operator and/or the assistant chief operator.

ii. For Grade 1I (one, industrial) systems, as defined in 257 CMR 2.11, the chief operator and assistant chief operator of the IWTS shall be Massachusetts certified wastewater treatment plant operators with a grade equal to or greater than Grade 1I (one, industrial).

iii. For Grade 2I (two, industrial) systems, the chief operator of the IWTS shall be a Massachusetts certified wastewater treatment plant operator with a grade equal to or greater than Grade 2I (two, industrial). The assistant chief operator of the IWTS shall be a Massachusetts certified wastewater treatment plant operator with a grade equal or greater than a Grade 1I (one, industrial).

iv. For a biotechnology operation with an IWTS graded at a level greater than 2I (two, industrial) and less than a Grade 5 (five), the chief operator of the IWTS shall be a Massachusetts certified wastewater treatment plant operator with a grade equal to or greater than the grade of the IWTS. The assistant chief shall, at a minimum, be a Massachusetts certified wastewater treatment plant operator with a grade equal to, but not less than, one grade below the grade of the treatment system.

The following table summarizes 17.09(2)(a) i through iv.

IWTS Grade	Required Minimum Chief Operator Certification Level	Required Minimum Assistant Chief Operator Certification Level
1I	1I	1I
2I	2I	1I
>2I and < 5	> or = IWTS Grade	>or = (IWTS Grade) - 1

(b) The owner or operator of any IWTS shall prepare a staffing plan in accordance with 314 CMR 12.04(3). A copy of the staffing plan shall be kept at the site of the IWTS and shall be made available for review by the Department and the local sewer authority upon request.

(c) The owner or operator of any biotechnology operation with an IWTS shall provide adequate certified operator personnel to ensure that the IWTS is properly operated, maintained, and in compliance with applicable effluent limits at all times.

i. For the purposes of 314 CMR 17.09(2)(c), adequate certified operator personnel for an IWTS that is not alarmed and is not automated shall mean:

a. For a Grade 1I (one, industrial) IWTS that is operated eight (8) hours or more per calendar day, a certified operator at least equal to the IWTS grade shall be present during at least 8 hours per calendar day that the treatment system is operational;

b. For a Grade 2I (two, industrial) IWTS or higher that is operated more than eight (8) hours per calendar day, a certified operator at least equal to the IWTS grade shall be present at least 8 hours per calendar day that the system is operational and, at a minimum, a certified operator no more than one grade lower than the IWTS grade shall be present during all operations;

c. For an IWTS that is operated less than 8 hours per calendar day, a certified operator at least equal to the IWTS grade shall be present during all operations; and

ii. For the purposes of 314 CMR 17.09(2)(c), adequate certified operator personnel for an alarmed IWTS, regardless of the grade, shall mean that a certified operator at least equal to the IWTS grade shall visit and monitor the treatment system daily and shall be available to address problems any time during treatment system operation.

iii. For the purposes of 314 CMR 17.09(2)(c), adequate certified operator personnel for a fully automated IWTS shall mean

a. For a Grade 1I (one, industrial) fully automated IWTS, a certified operator at least equal to the IWTS grade shall visit and monitor the system twice weekly, preferably on Monday and Friday, and shall be available to address problems any time during treatment system operation.

b. For a Grade 2I (two, industrial) fully automated IWTS, a certified operator at least equal to the IWTS grade shall visit and monitor the treatment system daily and shall be available to address problems any time during treatment system operation.

iv. A biotechnology operation may request the Department's approval pursuant to 314 CMR 12.04(3) of a staffing plan that differ from the requirements in 310 CMR 17.09(3)(c)i.-iv. above.

The following table summarizes 17.09(2)(c) i through vi.

Facility Grade or Type	Duration of Facility Treatment System Operation	Required Operator Certification Level	Minimum Time the Certified Operator Must be Present at the Treatment System
1I	> or = 8 hours	> or = Facility Grade	8 Hours
> or = 2I	> or = 8 Hours	> or = Facility Grade	8 Hours
> or = 2I	> or = 8 Hours	> or = Grade (Facility) - 1	8 Hours
Any Grade	< 8 Hours	> or = Facility Grade	At all Times the IWTS is Operational
Alarmed IWTS of Any Grade	Any Amount of Operational Time	> or = Facility Grade	Daily Visits and On-call During All Operations
1I Fully Automated IWTS	Any Amount of Operational Time	> or = Facility Grade	2 Visits per Week, Monday & Friday Preferred and On-call During All Operations
2I Fully Automated IWTS	Any Amount of Operational Time	> or = Facility Grade	Daily Visits and On-call During All Operations

(d) For non automated Grade 1I or 2I (one or two, industrial) IWTS, the following activities shall be done by, or under the direct supervision of an appropriately licensed operator of the IWTS:

i. chemical preparation;

ii. equipment maintenance and calibration;

iii. instrumentation adjustments;

iv. preventive maintenance tasks identified in the IWTS Operations and Maintenance (O&M) Manual required under 314 CMR 17.10;

v. corrective maintenance tasks necessary to assure proper IWTS operation; and

vi. any sampling events exclusive of automatic pH monitoring.

17.10 Operation and Maintenance Requirements for Industrial Wastewater Treatment Systems (IWTS)

(1) The owner or operator of a biotechnology operation shall prepare an operation and maintenance (O&M) manual for the IWTS to be used by its operations personnel. The matters to be adequately addressed in the O&M manual shall include but not be limited to:

(a) Procedures for the IWTS, wastewater collection, treatment operations, equipment cleaning, calibration, equipment replacement, emergencies, chemical make-up, personnel, and equipment safety;

(b) Procedures for documentation of all maintenance, calibration, and effluent analyses; and

(c) Training programs regarding the biotechnology operation and the operation and maintenance of the IWTS.

(2) A copy of the O&M manual shall be kept on-site and made available for review by the Department and the local sewer authority upon request.

17.11 Recordkeeping for the Industrial Wastewater Treatment Systems

(1) The following records shall be maintained at the biotechnology operation and be made available for review by the Department and the local sewer authority upon request for as long as the IWTS is in operation, regardless of any change of ownership:

(a) All permits required by federal, state, and local authorities;

(b) The current facility plan for the treatment system and any related engineering evaluation reports;

(c) As built construction plans of the treatment system;

(d) Up to date equipment specifications for the treatment system; and

(e) The current operation and maintenance manual.

(2) The following records shall be maintained at the biotechnology operation for a minimum of three (3) years and shall be made available to the Department and the local sewer authority upon request:

(a) Operation and maintenance records, including but not limited to a daily operation log, a routine inspection log, an equipment maintenance log, and a chemical and supply inventory;

(b) Sampling and analysis records, including but not limited to chain of custody records, raw data, quality assurance and quality control results, and analytical reports; and

(c) Staff training records, including but not limited to, dates of training, names of instructors and trainees, training material, training results (e.g., test scores and pass rates), and the instructor's comments on each trainee.

17.12 Reporting

(1) Within thirty days of each monitoring event required pursuant to 314 CMR 17.07(3)(a), a biotechnology operation subject to 314 CMR 17.00 shall submit a monitoring report on all the parameters, including pH, required to be sampled under 314 CMR 17.07 to the local sewer authority and, upon request, to the Department.

(2) A biotechnology operation subject to 314 CMR 17.00 shall report to the local sewer authority, and, upon request to the Department, all exceedances of the effluent limits in 314 CMR 17.06 within 15 days of their occurrence and include a description of corrective actions and a schedule for returning to compliance.

(3) Registration, List of Toxics, and One-time Compliance Certification Statement

(a) Biotechnology operations subject to 314 CMR 17.00 shall file a *Registration and One-time Compliance Certification Statement* with the Department, the local sewer authority, and the Board. For an existing biotechnology operation, the Report shall be filed within 90 days from the date of promulgation of 314 CMR 17.00. For a new biotechnology operation, the Report shall be filed 30 days prior to any discharge of industrial wastewater to the POTW. The Registration shall include but not be limited to the following information and shall be on a form as prescribed by the Department:

i. Registration Information. For the purpose of notifying the Department, the local sewer authority, and the Board that a biotechnology operation is being regulated under 314 CMR 17.00, the biotechnology operation shall, at a minimum, provide the following registration information:

a. The name and location of the biotechnology operation and related contact information;

b. A description of the biotechnology operation;

c. A schematic diagram of the IWTS used by the biotechnology operation and the grade of the IWTS; and

d. The number, identity, and grades of certified wastewater treatment facility operators used by the biotechnology operation.

ii. A list of those toxic chemicals, contained in 360 CMR 10.00, Appendices A and B, that are used at the biotechnology operation and have the potential to be discharged to the POTW.

a. In any year in which a new toxic chemical, contained in 360 CMR 10.00, Appendices A and B, is used that has the potential to be discharged to the POTW, an updated list of toxic chemicals shall be provided to the Department on or before December 31 of that year.

iii. One-time Compliance Certification Statement. An authorized representative of the biotechnology operation shall make and include the following certification in the Report:

"I, [name of authorized representative], attest under the pains and penalty of perjury:

a. that I personally examined and am familiar with the information contained in this submittal;

b. that based on my inquiry of those individuals responsible for obtaining the information, the information contained in this submittal is to the best of my knowledge, true, accurate, and complete;

c. that I have reviewed and understand the requirements of 314 CMR 17.00 and that the [name of the biotechnology operation] meets the criteria for regulation under 314 CMR 17.03(1);

d. that personnel of the biotechnology operation responsible for assuring compliance with the requirements of 314 CMR 17.00 have also reviewed and understand the requirements of this regulation;

e. that systems to maintain compliance with 314 CMR 17.00 are in place at the biotechnology operation and will be maintained; and

f. that I am fully authorized to make this attestation on behalf of the biotechnology operation, and that I am aware that there are significant penalties, including but not limited to, possible fines and imprisonment for submitting false, inaccurate, or incomplete information."

17.13 Enforcement

(1) The Department may enforce the provisions of 314 CMR 17.00, through the issuance of orders and/or civil administrative penalties, pursuant to its authority under M.G.L. c. 21, §§ 26 through 53, M.G.L. c. 21A, § 16 and 310 CMR 5.00, and other applicable laws and regulations, provided that the Department shall not be responsible for enforcing a biotechnology operation's compliance with local effluent limits required to be met by the biotechnology operation pursuant to local sewer use regulations.

(2) The Department may require any biotechnology operation to obtain the permits and plan approvals for activities that are otherwise exempt under 314 CMR 17.00 from such permits and plan approvals if the Department determines that such action is necessary to protect the public health, safety, and the environment.

(3) The Department may require any person to provide information as the Department may reasonably require to determine whether that person is subject to M.G.L. c. 21, §§ 26 through 53 or 314 CMR 17.00 or has violated M.G.L. c. 21, §§ 26 through 53 or 314 CMR 17.00.

Regulatory Authority

314 CMR 17.00 is promulgated pursuant to the Department's authority under M.G.L. c. 21, §§ 26 through 53.

IX. Proposed Amendment: 257 CMR 2.00 Certification of Operators of Wastewater Treatment Facilities

1. The existing paragraph in 2.04 should be numbered subsection (1).

2. A new subsection (2) will be added:

> (2) Persons who manage, operate and maintain a wastewater treatment facility in compliance with the certified operator and classification of wastewater treatment facilities provisions in 314 CMR 17.00 (the Department of Environmental Protection's Industrial Wastewater Management and Discharge Requirements for Biotechnology Facilities) are exempt from obtaining Board approval for such certified operator and facility classification requirements as specified in 314 CMR 17.00.